

# Omalizumab (Xolair®)

## Criteria for Use in CHRONIC IDIOPATHIC OR SPONTANEOUS URTICARIA (CIU/CSU)

### May 2015

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

*The Product Information should be consulted for detailed prescribing information.*

*See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vawww.pbm.va.gov> for further information.*

**Exclusion Criteria** If a box to ANY item below is checked, the patient should NOT receive Omalizumab.

☐ Prior severe hypersensitivity reaction to omalizumab or any of its ingredients

**Inclusion Criteria** The answers to ALL of the following must be fulfilled in order to meet criteria.

☐ Patient has received a diagnosis of severe, treatment refractory chronic idiopathic urticaria.

☐ Patient is receiving care from VA Allergy Specialist, Dermatologist or locally designated expert in the management of Allergic Conditions.

☐ Patient has an epinephrine pen with them at the time of the injection and for at least 24 hours after and has been advised on its proper use verbally and/or in writing.

☐ Patient continues to have unacceptable symptoms despite a therapeutic trial of at least two non-sedating H1-antihistamines (Therapeutic trial is defined as: at least 2 weeks at usual doses and then titrated to up to 4 times the maximum daily dose and followed for 1-4 weeks after doses are maximized for improvement in symptoms, as tolerated).

☐ Patient continues to have unacceptable symptoms despite a therapeutic trial of montelukast, if appropriate (at least 4 weeks).

☐ Provider has strongly considered and discussed with their patient the use of low dose cyclosporine (e.g., 1-3 mg/kg/d) to manage patients without contraindications to cyclosporine therapy.

#### Cyclosporine in Chronic Idiopathic Urticaria-Summary of the Evidence

*\*Approximately 25% of refractory patients treated with cyclosporine in clinical trials remain in remission once treatment is stopped while symptoms return to near baseline after treatment with omalizumab is discontinued.*

*\*Approximately 60-70% of patients with refractory CIU respond to cyclosporine or omalizumab. Response is reported within the first week with daily cyclosporine and omalizumab 300 mg q4 weeks and within 2 weeks for omalizumab 150 mg q4 weeks.*

#### **Dosage and Administration**

##### **Omalizumab:**

- 150 to 300 mg subcutaneously every 4 weeks. Consider initiating 150 mg every 4 weeks and then increasing to the 300 mg dose if symptoms persist.
- The dose of omalizumab is not dependent upon free or total serum IgE or body weight.
- Consult the prescribing information for instructions on preparation and administration of omalizumab.

**Note: Administer omalizumab in a healthcare setting. No more than 150 mg should be injected into a single site. If the 300 mg dose is used, the dose should be divided into two injections and given at two separate sites.**

#### **Monitoring**

- Patients should be monitored for hypersensitivity reactions (e.g., anaphylaxis) for an appropriate amount of time after each injection. (Boxed warning). More than 50% of severe hypersensitivity reactions occurred within two hours after the dose.
- Monitor for symptom improvement.

#### **Issues for Consideration**

- Medication guides are to be provided with each omalizumab injection. Patients should be instructed to read the medication guide prior to each dose of omalizumab.
- Healthcare professionals should be prepared to manage life-threatening anaphylaxis.
- Patients should be educated on recognizing the signs and symptoms of severe hypersensitivity reactions and anaphylaxis.
- Patients should carry the EPI pen auto-injector with them at the time of the injection and have it readily available for 24 hours afterwards since anaphylaxis has been reported to occur up to 24 hours after the injection. Patient has been instructed verbally and/or in writing on the proper use of the EPI pen auto-injector.

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Updated versions may be found at <http://www.pbm.va.gov> or <https://vawww.cmopnational.va.gov/cmop/PBM/default.aspx>

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- Anaphylaxis can occur after any dose even if previous doses were well tolerated (39% of reported cases occurred after the first dose).
  - If a severe hypersensitivity reaction occurs, omalizumab should be discontinued.
  - A 5-year post-marketing observational safety study (EXCELS) conducted in patients with moderate to severe persistent asthma showed a higher risk of adverse cardiovascular and cerebrovascular events in patients receiving omalizumab versus non-treated patients. Because of study limitations, the magnitude of risk could not be quantified.
  - The same 5-year post-marketing observational safety study (EXCELS) did not find an increased risk for malignancy in omalizumab treated versus non-treated patients. However, because of limitations of the study, the FDA was unable to rule out the possibility of an increased risk for cancer with omalizumab.
  - Patients receiving omalizumab and traveling to endemic parasitic regions should be monitored for such infections. A one-year study conducted in Brazil found that 53% of patients receiving omalizumab developed an infection compared to 42% of placebo controls (OR 1.96 [95% CI 0.88-4.36])
  - The optimal duration of therapy for CIU/CSU is unknown and has not been evaluated beyond 24 weeks. Therefore, clinicians are advised to periodically assess the need for continuation of therapy.

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#### **Renewal Criteria**

- Treatment with omalizumab should be discontinued if an inadequate or no response is reported after a therapeutic trial (e.g., 2-3 doses).
- Therapy should be individualized with the goal of reducing symptoms of urticaria to satisfy the patient and to improve quality of life.

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